K131424

JUL 12 2013

5. 510(k) Summary

5.1. Identification of Submitter:

Submitter:	Hinacom Software and Technology Ltd. Co.
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Summary Date: 12/11/2012

5.2. Identification of Product:

Trade name:	miPlatform medical imaging suite
Common/Usual Name:	Picture Archiving and Communications System
Classification Name:	System, Image Processing Radiological (21 C.F.R. 892.2050, LLZ)
Device Classification:	Class II
Manufacturer:	Hinacom Software and Technology Ltd. Co.

5.3. Indication for Use

miPlatform is an internet-based image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians.

The system is a software package that is used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data. The software performs digital image processing, analysis, reviewing, communication and storage.

miPlatform supports receiving, sending, printing, storing and displaying studies received from the following modality types via DICOM: CT, MR, NM, US, XA, PET, DX, DR, RF, RT, MG, SC, VL, as well as hospital/radiology information systems and any other information systems that support DICOM 3.0 standard.

miPlatform also supports multidimensional image visualization, measurement and analysis tools, and reporting algorithms. The user interface is designed to follow typical clinical workflow patterns to process, review, validate/edit and analyze digital images. The software supports the following image analysis options:

Vessel Analysis is an option intended for viewing or displaying vascular obstructive disease by providing a non-invasive survey of a patient's coronary or peripheral arteries. Physicians can select any artery to view the following anatomical references: the highlighted vessel in 3D, two rotate-able curved MPR vessel views displayed at angles orthogonal to each other, and cross sections of the vessel. Physicians can manually measure the lumen width to obtain percentage stenosis calculations. In addition, clinicians can manually measure vessel length along the centerline in standard curved MPR views and examine Houndsfield unit or signal intensity statistics.

Coronary Calcium Scoring is an option intended for cardiac scoring from CT image derived measurements, including non-invasive detection and quantification of atherosclerotic plaque. Physicians can use semi-automatic tools in Coronary Calcium Scoring to mark calcified lesions of coronary arteries, and automated computation of Agatston scoring will be performed and presented in a report.

miPlatform supports a real-time image-based conference option with integrated audio/video capability. Multiple users may log into the system and participate in the conference from different locations via internet connection.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted

using an FDA cleared monitor that meets technical specifications reviewed and accepted by FDA.

5.4. Software Development

Hinacom certifies that the miPlatform software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software developed for this product is used to provide diagnostic quality images and associated information to the intended users.

5.5. Identified technological characteristics with predicate device:

Device	miPlatform	iSite PACS	Vitrea, Version 4.0
Window O.S. – Client	Yes	Yes	Yes
Web-based Client	Yes	No	No
DICOM Image Import/Export. (Support DICOM Storage, Query/Retrieve, Print)	Yes	Yes	Yes
Image Archive. (DICOM image storage and management.)	Yes	Yes	Yes
2D Image Reading. (Support image annotation, measurement and cine.)	Yes	Yes	Yes
3D Rendering. (Include MPR, MIP, minIP and CPR)	Yes	No	Yes
CTA Vessel Analysis. (Support Vessel Probe, Vessel CPR.)	Yes	No	Yes
CT Calcium Scoring. (Support lesion labeling, Agatston Scoring.)	Yes	No	Yes
Video Conference	Yes	No	No

Technological Characteristics:

The miPlatform has the same technological characteristics and is similar in overall design, principal of operation and configuration compared to the predicates.

Performance

Support of the substantial equivalence of the miPlatform device was provided as a result of software validation, which confirms all features of the miPlatform device were compliant with the software requirements.

Basis for Determination of Substantial Equivalence:

Upon reviewing and comparing intended use, design, principle of operation and overall technological characteristics, the miPlatform is determined by HINACOM Software, Ltd. to be substantially equivalent to existing legally marketed devices.

Testing

miPlatform is tested successfully with reference to its Software Requirements Specification, as well as design verification and validation documents and Traceability Matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the miPlatform, which is found to be safe and effective and substantially equivalent to the currently-cleared predication devices.

Testing involved system level functionality test, segmentation accuracy test, measurement accuracy test, interfacing test, usability test, serviceability test, labeling test, as well as the test for risk mitigation method analyzed and implemented in the risk management process. In addition, we conducted the performance comparison testing on retrospective images to help demonstrate that the proposed device is substantially equivalent to the predicate devices.

Pass/Fail criteria were based on the requirements and intended use of the product. Test results showed that all tests successfully passed.

5.6. Determination of Substantial equivalence:

Summary of Non-Clinical Tests:

The miPlatform and its components comply with the following voluntary standards: NEMA PS3.1-3.18(2008) Digital Imaging and Communication in Medicine (DICOM) Set.

The performance of the software is tested in accordance with Hinacom's design control procedures to demonstrate intended performance. Potential hazards are controlled via risk management processes and verification and validation testing. Instructions for use are provided to facilitate intended operation.

miPlatform was designed in compliance with the following Process Standards:

- DICOM PS 3.2. Digital Imaging and Communications in Medicine – Conformance Standard

The following quality assurance measures were applied to the development of the device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (verification)
- Safety testing (verification)
- Final acceptance testing (validation)

Performance Data from nonclinical Testing:

Designated individuals performed all verification and validation activities and results demonstrated that the predetermined acceptance criteria were met. The system passed all testing criteria.

Extensive performance tests had been conducted regarding the technological characteristics aspects. All tests had been passed successfully.

Applicable Standards:

DICOM standard for image data format and communication

5.7. Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. It is the user's responsibility to ensure that display quality, environmental lighting and other possible distractions are consistent with the clinical environment. The hardware components specified are all "off the shelf" computer components.

5.8. Comparison with Predicate Devices

miPlatform is substantially equivalent to several software applications that display, visualize, analyze and measure images and regions of interest. The predicate devices are iSite PACS (K042292) and Vitrea, Version 4.0 (K071331) which have been classified under 21 CFR 892.2050 as a Class II medical device.

miPlatform is substantially equivalent to the identified predicate devices. All of these devices offer the visualization techniques, measurement and analysis tools which can be applied for more effective and accurate display, interpretation, and communication.

The miPlatform product is similar in characteristics, materials, and features, and has similar technological features, intended use and indications for use as the predicates, and does not pose any new issue of safety and effectiveness.

5.9. Conclusions

In summary, HINACOM software and technology, Ltd. is of the opinion that miPlatform does not introduce any new potential safety risk, is as effective and performs as well as devices currently on the market, and thus concludes that the miPlatform software is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 12, 2013

HINACOM Software and Technology, Ltd. Co.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K131424
Trade/Device Name: miPlatform medical imaging suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 16, 2013
Received: June 11, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131424

Device Name: miPlatform medical imaging suite

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Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subparts D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131424